K063686

Section 5 – 510 (k) Summary

(As required by 21 CFR 807.92(c) and 21 CFR 807.93)

DEC 2 0 2007

NAME OF SPONSOR:	DePuy Orthopaedics, Inc. 700 Orthopaedic Drive Warsaw, Indiana 46582 Establishment Registration Number: 1818910
510(K) CONTACT:	Rebecca Lennard Regulatory Affairs Associate II Telephone: (574) 372-5023 Facsimile: (574) 371-4987 Electronic Mail: RLennard@dpyus.jnj.com
ALTERNATE 510(K) CONTACT:	Nancy Friddle Team Leader, Regulatory Affairs Telephone: (574) 371-4923 Facsimile: (574) 371-4987 Electronic Mail: NFriddle@dpyus.jnj.com
DATE PREPARED:	September 14, 2006
PROPRIETARY NAME:	DePuy LPS Distal Femoral Component
COMMON NAME:	Distal Femoral Component
CLASSIFICATION:	Class II Device per 21 CFR 888.3560: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
DEVICE PRODUCT CODE:	87 JWH
SUBSTANTIALLY EQUIVALENT DEVICE:	DePuy LPS, K033959 DePuy Orthogenesis LPS System, K003182 Noiles Total Knee Prosthesis, K905810

DEVICE DESCRIPTION:

The subject DePuy LPS Distal Femoral Component is a modular component that is designed to replace the distal portion of the femur. Unlike primary knee systems, the LPS System is used when the amount of bone resection and replacement is extreme (e.g. in oncology cases or endstage revision).

The LPS Distal Femoral Component is manufactured from cobalt-chrome-molybdenum alloy and is available in two sizes, X-small low profile and XX-small, both in left and right configurations. The surface has a highly polished mirror finish for smooth articulation with the polyethylene component of the tibial plateau/hinge assembly and the resurfaced patella.

INTENDED USE AND INDICATIONS FOR USE:

Intended Use:
The DePuy LPS is intended for use in replacement of the mid-shaft portion of the femur, proximal, distal and/or total femur, and proximal tibia, especially in cases that require extensive resection and replacement.

Indications for Use:
The DePuy LPS is intended for use in replacement of the mid-shaft portion of the femur, proximal, distal and/or total femur, and proximal tibia, especially in cases that require extensive resection and replacement. Specific diagnostic indications for use include:

- malignant tumors (e.g., osteosarcomas, chondrosarcomas, giant cell tumors, bone tumors) requiring extensive resection and replacement;
- patient conditions of noninflammatory degenerative joint disease (NIDJD), e.g. avascular necrosis, osteoarthritis, and inflammatory joint disease (IJD), e.g., rheumatoid arthritis, requiring extensive resection and replacement;
- revision cases for a failed previous prosthesis requiring extensive resection and replacement;
- severe trauma requiring extensive resection and replacement.

The LPS is also intended for use in bone loss post-infection, where the surgeon has elected to excise the bone and replacement is required.

The S-ROM tibial tray and the non-porous coated straight and bowed stems are intended for cemented use only.

BASIS OF SUBSTANTIAL EQUIVALENCE:

The substantial equivalence of the LPS Distal Femoral Component is substantiated by its similarity:

- in indications for use to the DePuy LPS (K033959 cleared on July 1, 2004)

- in design, materials, packaging and sterilization to the Orthogenesis LPS Distal Femoral Replacement System (K003182 cleared on June 27, 2001) and the Noiles Total Knee Prosthesis femoral component (K905810 cleared on June 12, 1991).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 0 2007

DePuy Orthopaedics, Inc.
% Nancy S. Friddle
Project Manager, Regulatory
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

Re: K063686
Trade/Device Name: DePuy LPS Distal Femoral Component
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH
Dated: September 25, 2007
Received: September 26, 2007

Dear Ms. Friddle:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4 – Indications for Use Statement

510 (k) Number (if known): K063686

Device Name: DePuy LPS Distal Femoral Component

Indications for Use:

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- severe trauma requiring extensive resection and replacement.

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(Please do not write below this line. Continue on another page if needed.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Posted November 13, 2003)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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